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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,282	11/19/2003	Scott R. Presnell	00-49C1	8902

10117 7590 05/15/2007

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	**PAPER NUMBER**
1647	

MAIL DATE	DELIVERY MODE
05/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/717,282	**Applicant(s)** PRESNELL ET AL.	
	Examiner Fozia M. Hamud	**Art Unit** 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *02 February 2007*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,2 and 4-14*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments have not been found persuasive to overcome the rejection of claims 1-2 and 4-14 made under 35 U.S.C. 101 or made under 35 U.S.C. 112, first paragraph for resons of record.
Applicant argues that the Examiner has not made a prima facie case for holding lack of utility and failed to provide any evidence or sound scientific reasoning to refute the asserted utility. Applicant submits that upon reading the specification, one of skill in the art would appreciate that ZcytoRI8 is a member of the sufficiently conserved interleukin-17 related receptor family of proteins and would reasonably impute the same specific, substantial and credible utility to ZctyoRI8.

Applicant aslo argues that Zcytor18 is not merely a member of IL-17 receptor related family, but it bears significant homology with IL-17RD (SEF) and therefore, one having ordinary skill in the art would presume that Zcytor18 shares binding activity of SEF. Applicant submits that Zcytor18 is 97.6% homologous to SEF and has an extra 14 amino acid residues at amino acid residues 43-56 and also two other residues variations. Applicants assert that these differences exist because SEF is a splice variant of Zcytor18. Applicant maintains that in spite of these differences, one having ordinary skill in the art would still presume that Zcytorl8 and SEF retain the same ligand binding properties. Applicant also argues that the instant specification provides a second specific, substantial, and credible utility, because "Zcytorl8 gene resides in human chromosome 3p14.3". Therefore, "nucleic acid probes that encode Zcytorl8, or a fragment thereof, can be used to detect gross aberrations in chromosome 3"; and thereby, the nucleic acid probes can be used to detect a correlating disease a correlating disease. Thus, Applicant concludes that the invention of claims 1-14 is useful.
These arguments have been fully considered, but are not deemed persuasive. Although Applicant argues that the Zcyror18 of the instant invention is a splice variant of sef, (IL-17RD), because it shares high degree of homology to sef, the specification does not disclose that the two proteins display the same biological activities. Recently it has been found that there is an alternative splice variant of human sef, known as hsef-b, (see Preger et al, PNAS, 2004, Vol.101, No.5, pages 1229-1234, especially, see abstract, page 1230, column 2). Human sef-b consists of 707 amino acid residues compared to the 739 of human sef-a, displays a restricted pattern of expression in human tissues, inhibits FGF-induced cell proliferation and prevents the activation of mitogenic response of several FGF family members. Thus the two hsef isoforms, although they are alternate splice variants exhibit different biochemical properties, subcellular localization and specificity, (see page 1234, column 2). Therefore, although it is possible that the Zcytor18 of the instant invention is yet another splice variant of sef, however, the skilled artisan would not be able to use the claimed invention at the time the current application was filed, because the instant invention needs further characterization to ascertain whether the Zcytor18 is a sef splice variant, which activities of sef does it display or what is its physiological role. However, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. Finally, it is acknowledged that the specification discloses that the zcytor18 gene resides at human chromosome 3p14.3, however, neither the claimed nucleic acid nor a fragment thereof, can be used to detect gross aberrations in chromosome 3 or to detect any disease or disorder, because the specification fails to establish a link between the claimed nucleic acid and a physiological condition, disease or disorder. The specification does not disclose the physiological or biological significance of the claimed nucleotides or the encoded proteins, therefore no meaningful information will be obtained from tracking the level of expression of the claimed nucleotide. Without a disclosure of a particular disease state in which the claimed nucleic acid are expressed at an altered level or form, it would be impossible to use it in a diagnostic manner. Accordingly, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility..

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER